K013576

PERIscope™
510(k) Summary of Safety and Effectiveness

JAN 2 5 2002

Company:
Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact:
Name: Doug Kentz
Title: Regulatory Affairs Associate II

Date Prepared:
October 26, 2001

Name of Device:
Trade Name: PERIscope Optical Dissector
Classification Name: Laparoscope, General and Plastic Surgery

Predicate Device:

Cardiovations™ ClearGlide™ Optical Vessel Dissector, cleared under K973139 on November 13, 1997.

Device Description:

The PERIscope Optical Dissector consists of a handle, a scope retainer clip, a cannula and a dissecting tip. The dissecting tip dissects tissue and creates a cavity that allows instrument passage. The dissecting tip allows visualization during insertion, tunneling, and dissection. The device is designed to be used with a trocar. The instrument is compatible with a 0° rigid endoscope that has a maximum diameter of 5.5 mm and is 290 mm to 300 mm in length.

Intended Use:

The PERIscope Optical Dissector is intended for dissection of connective tissue and the creation of an operative cavity in the extraperitoneal spaces and subcutaneous areas. The instrument has application in various general surgical procedures, such as laparoscopic hernia repair.

Technological Characteristics:

The PERIscope Optical Dissector is similar to the predicate device with respect to design and intended use. Both devices are also sterile, single patient use devices.

Performance Data

Preclinical testing was performed to ensure the device performs as intended when used according to the instructions for use. Animal testing demonstrated satisfactory performance of the PERIscope Optical Dissector during laparoscopic surgical procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2002

Mr. Doug Kentz
Regulatory Affairs Associate II
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K013576
Trade/Device Name: PERIscope Optical Dissector
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: October 26, 2001
Received: October 29, 2001

Dear Mr. Kentz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K013576

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Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013576